The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section74(1) and (4) of the Deregulation and Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the international application filed on 15 April 2003 under the Patent Cooperation Treaty at the UK Receiving Office. The application was allocated the number PCT/GB2003/01606.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or the inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

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Signed Philip Jones

CERTIFIED COPY OF
PRIORITY DOCUMENT

Date: January 15, 2007

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

PCT/GB 2003 / 0 0 1 6 0 6
International Application No.

15 APRIL 2003 15-04-03
International Filing Date

United Kingdom Patent Office
PCT International Application
Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference (if desired) (12 characters maximum) DPW/Y804

Box No. I TITLE OF INVENTION

A TRANSVERSE SUSPENSION DEVICE

Box No. II APPLICANT ☐ This person is also inventor

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

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Telephone No.

Facsimile No.

Teleprinter No.

Applicant's registration No. with the Office

State (that is, country) of nationality: GB

State (that is, country) of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

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This person is:
☐ applicant only
☒ applicant and inventor
☐ inventor only (If this check-box is marked, do not fill in below.)

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State (that is, country) of residence: GB

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

WALSH, David Patrick; NEILL, Alastair William; SHERRARD-SMITH, Hugh; PIDGEON, Robert John; BRIERLEY, Anthony Paul; BRANDON, Paul Laurence; CHUGG, David John; ROBINSON, Ian Michael; WADDINGTON, Richard; PARKINSON, Neil Scott; FRITH, Richard William; APPLETON, Ben; MOY, David; JACKSON, Nicholas Andrew. ALL OF: APPLEYARD LEES, 15 Clare Road, Halifax, HX1 2HY, England** GB

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☐ **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Form PCT/RO/101 (first sheet) (March 2001; reprint January 2003) *See Notes to the request form*

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PCT/GB 2003 / 001606

Sheet No. ...2...

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

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This person is:
- [ ] applicant only
- [x] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality: IT

State *(that is, country)* of residence: GB

This person is applicant for the purposes of: [ ] all designated States [ ] all designated States except the United States of America [x] the United States of America only [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: [ ] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: [ ] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

Applicant's registration No. with the Office

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

This person is applicant for the purposes of: [ ] all designated States [ ] all designated States except the United States of America [ ] the United States of America only [ ] the States indicated in the Supplemental Box

[ ] Further applicants and/or (further) inventors are indicated on another continuation sheet.

"deleted RO/GB • added RO/GB"

PCT/GB 2003 / 0 0 1 6 0 6

Box No. V DESIGNATION OF STATES *Mark the applicable check-boxes below; at least one must be marked.*

The following designations are hereby made under Rule 4.9(a):

Regional Patent

☒ AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZM Zambia, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

☒ EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

☒ EP **European Patent:** AT Austria, BE Belgium, BG Bulgaria, CH & LI Switzerland and Liechtenstein, CY Cyprus, CZ Czech Republic, DE Germany, DK Denmark, EE Estonia, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, SI Slovenia, SK Slovakia, TR Turkey, and any other State which is a Contracting State of the European Patent Convention and of the PCT

☒ OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GQ Equatorial Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

☒ AE United Arab Emirates	☒ GM Gambia	☒ NZ New Zealand
☒ AG Antigua and Barbuda	☒ HR Croatia	☒ OM Oman
☒ AL Albania	☒ HU Hungary	☒ PH Philippines
☒ AM Armenia	☒ ID Indonesia	☒ PL Poland
☒ AT Austria	☒ IL Israel	☒ PT Portugal
☒ AU Australia	☒ IN India	☒ RO Romania
☒ AZ Azerbaijan	☒ IS Iceland	☒ RU Russian Federation
☒ BA Bosnia and Herzegovina	☒ JP Japan	
☒ BB Barbados	☒ KE Kenya	☒ SC Seychelles
☒ BG Bulgaria	☒ KG Kyrgyzstan	☒ SD Sudan
☒ BR Brazil	☒ KP Democratic People's Republic of Korea	☒ SE Sweden
☒ BY Belarus		☒ SG Singapore
☒ BZ Belize	☒ KR Republic of Korea	☒ SK Slovakia
☒ CA Canada	☒ KZ Kazakhstan	☒ SL Sierra Leone
☒ CH & LI Switzerland and Liechtenstein	☒ LC Saint Lucia	☒ TJ Tajikistan
☒ CN China	☒ LK Sri Lanka	☒ TM Turkmenistan
☒ CO Colombia	☒ LR Liberia	☒ TN Tunisia
☒ CR Costa Rica	☒ LS Lesotho	☒ TR Turkey
☒ CU Cuba	☒ LT Lithuania	☒ TT Trinidad and Tobago
☒ CZ Czech Republic	☒ LU Luxembourg	
☒ DE Germany	☒ LV Latvia	☒ TZ United Republic of Tanzania
☒ DK Denmark	☒ MA Morocco	☒ UA Ukraine
☒ DM Dominica	☒ MD Republic of Moldova	☒ UG Uganda
☒ DZ Algeria		☒ US United States of America
☒ EC Ecuador	☒ MG Madagascar	
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☒ ES Spain		☒ VC Saint Vincent and the Grenadines
☒ FI Finland	☒ MN Mongolia	☒ VN Viet Nam
☒ GB United Kingdom	☒ MW Malawi	☒ YU Yugoslavia
☒ GD Grenada	☒ MX Mexico	☒ ZA South Africa
☒ GE Georgia	☒ MZ Mozambique	☒ ZM Zambia
☒ GH Ghana	☒ NO Norway	☒ ZW Zimbabwe

Check-boxes below reserved for designating States which have become party to the PCT after issuance of this sheet:

☒ NI Nicaragua	☐	☐
☐	☐	☐

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

PCT/GB 2003 / 0 0 1 6 0 6

Box No. VI PRIORITY CLAIM

The priority of the following earlier application(s) is hereby claimed:

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country or Member of WTO	regional application:* regional Office	international application: receiving Office
item (1) 16/4/2002 16 April 2002*	0208667.6	GB		
item (2)				
item (3)				
item (4)				
item (5)				

☐ Further priority claims are indicated in the Supplemental Box.

The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office)* identified above as:

☐ all items ☒ item (1) ☐ item (2) ☐ item (3) ☐ item (4) ☐ item (5) ☐ other, see Supplemental Box

** Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)):* ....

.....

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):*

ISA / .....

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority):*

Date *(day/month/year)* Number Country *(or regional Office)*

added Rule 13

Box No. VIII DECLARATIONS

The following declarations are contained in Boxes Nos. VIII (i) to (v) *(mark the applicable check-boxes below and indicate in the right column the number of each type of declaration)*: Number of declarations

☐ Box No. VIII (i)	Declaration as to the identity of the inventor	:
☐ Box No. VIII (ii)	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	:
☐ Box No. VIII (iii)	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	:
☐ Box No. VIII (iv)	Declaration of inventorship (only for the purposes of the designation of the United States of America)	:
☐ Box No. VIII (v)	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	:

PCT/GB 2003 / 0 0 1 6 0 6

Box No. IX CHECK LIST; LANGUAGE OF FILING

This international application contains:

(a) **in paper form**, the following number of sheets:

request (including declaration sheets)	:	5
description (excluding sequence listings and/or tables related thereto)	:	17
claims	:	4
abstract	:	1
drawings	:	10
Sub-total number of sheets	:	37
sequence listings	:	
tables related thereto	:	
(for both, actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (c) below)		
Total number of sheets	:	37

(b) ☐ **only in computer readable form** (Section 801(a)(i))
- (i) ☐ sequence listings
- (ii) ☐ tables related thereto

(c) ☐ **also in computer readable form** (Section 801(a)(ii))
- (i) ☐ sequence listings
- (ii) ☐ tables related thereto

Type and number of carriers (diskette, CD-ROM, CD-R or other) on which are contained the
- ☐ sequence listings: .....
- ☐ tables related thereto: .....

(additional copies to be indicated under items 9(ii) and/or 10(ii), in right column)

This international application is **accompanied** by the following item(s) *(mark the applicable check-boxes below and indicate in right column the number of each item)*: — Number of items

1. ☒ fee calculation sheet : 1
2. ☐ original separate power of attorney :
3. ☐ original general power of attorney :
4. ☐ copy of general power of attorney; reference number, if any: ..... :
5. ☐ statement explaining lack of signature :
6. ☐ priority document(s) identified in Box No. VI as item(s): ..... :
7. ☐ translation of international application into *(language)*: ..... :
8. ☐ separate indications concerning deposited microorganism or other biological material :
9. ☐ sequence listings in computer readable form *(indicate type and number of carriers)*
   - (i) ☐ copy submitted for the purposes of international search under Rule 13*ter* only (and not as part of the international application) :
   - (ii) ☐ *(only where check-box (b)(i) or (c)(i) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Rule 13*ter* :
   - (iii) ☐ together with relevant statement as to the identity of the copy or copies with the sequence listings mentioned in left column :
10. ☐ tables in computer readable form related to sequence listings *(indicate type and number of carriers)*
    - (i) ☐ copy submitted for the purposes of international search under Section 802(b-*quater*) only (and not as part of the international application) :
    - (ii) ☐ *(only where check-box (b)(ii) or (c)(ii) is marked in left column)* additional copies including, where applicable, the copy for the purposes of international search under Section 802(b-*quater*) :
    - (iii) ☐ together with relevant statement as to the identity of the copy or copies with the tables mentioned in left column :
11. ☐ other *(specify)*: ..... :

Figure of the drawings which should accompany the abstract: 1	**Language of filing of the international application:** English

Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

David Patrick Walsh
Authorised Representative

15.4.03

For receiving Office use only

1. Date of actual receipt of the purported international application: 15 APRIL 2003 15/04/03	2. Drawings: ☑ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): ISA /	6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PCT/GB 2003 / 0 0 1 6 0 6

A TRANSVERSE SUSPENSION DEVICE

The present invention relates to a transverse suspension device, in particular, but not exclusively, a transverse suspension screw for anterior cruciate ligament (ACL) fixation in the femoral tunnel.

Transverse securing devices are being increasingly used for secure fixation of ACL replacement grafts in the femoral tunnel during ACL reconstruction surgery. One such device known as the bone mulch ™ screw is available from Arthrotek®.

The bone mulch screw has a hollow body section with an opening at either end thereof. The tip of the screw is stepped having a sharp narrow leading section followed by a slightly wider trailing section. The trailing end of the tip is joined to the body section on one side of the said body section only, leaving a gap at the leading end of the body section so that bone mulch material can be forced therethrough and into the femoral tunnel after fixation. A suture passing loop must be located over the end of the partially inserted tip in the femoral tunnel and it is for this reason that the tip is stepped so that the leading end is as narrow as possible to maximise efficiency in the difficult step of locating a suture loop over the leading end of the bone mulch tip when it first protrudes into the femoral tunnel. Once the suture loop is in position, the bone mulch screw may be advanced further so that the stepped tip bores through the medial wall of the femoral tunnel until the thicker section of the tip fully extends transversely across the tunnel. The graft may then be pulled into the tunnel by passing it

over the transverse pin after attaching it to one end of the looped suture and pulling the other end. Unfortunately, because the graft must be pulled over the pin at the blind end of the femoral tunnel it is necessary to ream out bone from inside the femoral tunnel so as to create sufficient space for the graft to be pulled over the pin without becoming caught between the end of the femoral tunnel and the pin. By reaming out bone from the end of the femoral tunnel, the compression of the graft against the tunnel wall is decreased lengthening the process of healing and fixation. Furthermore, the looping of the suture is not a straightforward step and requires an arthroscopic view via the tibial tunnel and may also require several attempts before the loop is successfully located over the leading end of the tip.

Alternatives to such transverse suspension pins include interference cross pins which interfere against a bone block in bone-patella tendon-bone graft fixation. A suitable device for such procedures is the BiLok ™ screw. However, such techniques are not appropriate for pure tendon grafts such as the double-looped semitendinosus and gracilis (DLSTG) hamstring graft which is one of the strongest and stiffest grafts available and does not suffer from a number of complications associated with the bone-patella tendon-bone graft.

According to a first aspect of the present invention there is provided a transverse suspension device for ACL graft fixation in a femoral bone tunnel comprising a body section and a smooth head section forming the leading end of the device, the body and smooth head sections each being cannulated along the entire lengths thereof; the

head section comprising a recess engaging section extending proximally from the distal end thereof and operable to engage with a recess formed in the bone tunnel, and a graft loop support section between the recess engaging section and the body section adapted to stably support the graft loop thereover.

By the term stably support, is meant that the portion of the graft loop located over the loop support section is prevented from movement along the longitudinal axis of a femoral or other bone tunnel in which the device is located transverse thereto.

Preferably, the body section has a wider cross-section than the graft loop support section to provide an abutment surface at the proximal end of the graft loop support section. Preferably, the abutment surface provides a graft abutment in use, to urge the graft loop into contact with the opposite wall of a bone tunnel.

Advantageously, in use, the said abutment surface urges the graft loop onto the opposite wall of the femoral tunnel and thus the bone and the graft loop are encouraged to graft to each other.

Therefore, according to a second aspect of the present invention there is provided a transverse suspension device for ACL graft fixation in a femoral bone tunnel comprising a body section and a smooth head section forming the leading end of the device, the body and smooth head sections each being cannulated along the entire lengths thereof; the head section comprising a recess engaging section extending proximally from the distal end thereof

and operable to engage with a recess formed in the bone tunnel, and an abutment surface located between the body section and the recess engaging section adapted to urge the graft against the opposite wall of the bone tunnel in use.

Preferably in relation to the second aspect of the present invention the transverse suspension device comprises a graft loop support section which is, preferably, adapted to stably support the graft loop thereover. Preferably, the graft loop support section is located between the recess engaging section and the body section.

Preferably, the graft loop support section is of constant, preferably, circular, cross section. Typically, the head section is located on the same longitudinal axis as the body section.

Preferably, at least a part of the recess engaging section tapers outwardly from the leading end thereof. Preferably, the recess engaging section comprises a rounded nose section at the leading end thereof which, preferably, terminates the tapered section at the leading end of the device. Preferably, at least the major part of the recess engaging section is frustoconical.

Preferably, the device is cannulated along the entire length thereof. Preferably, the head section extends distally from the distal end of the body section.

Preferably, the body section is suitably adapted for secure fixation, in use, in a tunnel transverse to the femoral tunnel, preferably, by interference with the

tunnel wall. For instance, the body section may comprise a series of external protrusions such as ribs extending along the body section but tapering outwardly towards the trailing end to prevent the head of the device coming out of the femoral tunnel. Preferably, however, the body section is externally threaded so that the device may be conveniently screwed into position.

Preferably, the body section protrusions or threads provide a larger dimension for the body section between smaller dimension areas and, preferably, at least the larger dimension cross-section is wider than the dimension of the graft loop support section, more preferably, the smaller dimension cross-section areas of the body section are also wider than the graft loop support section.

As mentioned above, preferably, at least a part of the smooth head tapers outwardly from the leading end thereof to form a tapered section of the head. The smooth head may also include a non-tapered section between the tapered section and the body section previously described as the graft loop support section. Preferably, the widest diameter of the smooth head is less than the outer diameter of the body section. Preferably, the body section itself is not tapered but has a substantially uniform overall diameter along the length thereof subject to thread undulations or protrusions on the exterior surface thereof. The cannulated interior of the device may be wider at its trailing end to accommodate a suitable fixation device to assist location of the device in position.

Advantageously, by having the body and head section, cannulated, the device may be advanced along a guide wire and located under the loop of a graft pre-positioned in the femoral tunnel. An additional advantage is provided by the tapered head section which increasingly compresses the graft as it advances thereunder during fixation. A threaded or ribbed body section may still further compress the graft forwards and outwards when the smooth head is short enough to completely advance beneath the first loop so that then the body section impinges on the graft directly. However, compression is chiefly effected by an abutment surface at the distal end of the body section. Preferably, the abutment surface is in the form of a flange, which is, preferably, annular. Graft compression advantageously contributes to graft incorporation by assisting tunnel wall bonding of the graft. The abutment surface may be a flange.

Therefore, according to a third aspect of the present invention there is provided a method of ACL graft ligament fixation comprising the steps of:-

forming a femoral tunnel for graft fixation therein;

forming a transverse tunnel for intersecting the femoral tunnel;

locating a graft loop in the femoral tunnel in such a manner that the open face of the loop faces the intersection of the transverse tunnel,

passing at least a part of the head section of a transverse suspension device according to the first or

second aspect of the present invention through the graft loop via the transverse tunnel.

By passing the smooth head of the device through the graft loop, the graft is progressively compressed outwardly against the femoral tunnel walls before being stably located therein via the graft loop support section.

Preferably, after location of the graft loop in the femoral tunnel, a guide wire is advanced thereunder from the transverse tunnel using a suitable viewing device such as an arthroscope. The suspension device may then be passed along the guide wire.

Preferably, a dilation device is passed along the guide wire prior to the suspension device to dilate the loop in the graft after the guide wire is advanced thereunder, and, preferably, the dilation device is forced into the opposite wall of the femoral tunnel to create a recess therein.

The dilation device may then be removed and the suspension device may then be passed along the guide wire.

Preferably, the suspension device is advanced under the graft loop. Preferably, the recess engaging section is advanced into the recess in the opposite wall of the femoral tunnel and, preferably, the body section is advanced into the femoral tunnel. Preferably, the abutment surface of the body section urges the graft loop onto the opposite wall of the femoral tunnel.

Advantageously, the insertion of the dilation device opens the graft loop allowing the suspension device to pass freely thereunder.

Advantageously, the smooth surface of the head section prevents damage to the graft during its fixation and the method of locating the head section under the loop avoids the need for complex suture loop passing and looping steps. Furthermore, because the head section compresses the graft loop directly against the walls of the femoral tunnel in a single step, damage to the graft is minimised.

Preferably, the head of the device is advanced as far as the opposite wall of the femoral tunnel. The head may also be advanced into the opposite tunnel wall a short distance to provide more secure fixation, if required.

However, as the cannulation extends through the head section the leading tip of the head section does not typically terminate in a sharp point but is typically rounded into a convex tip with a centrally disposed cannular hole.

Preferably, the diameter of the cannular hole at the tip of the device is in the range 0.1-3mm, more preferably 0.5-1.5mm, most preferably 0.8-1.2mmm.

Preferably, the diameter of the cannular hole at the trailing end of the device is between 0.1-15.0mm, more preferably 1-10mm, most preferably 2-8mm.

Preferably, the length of the head section is between 1-25mm, more preferably between 2-20mm, most preferably between 5-15mm.

Preferably, the length of the body section is between 5-50mm, more preferably between 10-40mm, most preferably between 20-30mm.

Preferably, the maximum width of the head section is between 1-15mm, more preferably between 2-8mm, most preferably, between 3-8mm. An especially preferred width is 5-7mm.

Preferably, the width of the body section excluding any protrusions is between 2-15mm, more preferably, between 3-12mm, most preferably 5-12mm.

Preferably, the minimum width of the graft loop support section of the head section, is between 0.5-10mm, more preferably, between 2-8mm, most preferably, between 2-5mm.

Preferably, the trailing end of the device is adapted to receive a suitable tool for use during fixation of the device. The tool is preferably suitable to locate the device in the transverse tunnel via a push fit or screw fit mechanism.

An embodiment of the invention will now be described by way of example only and with reference to the accompanying drawings in which:

Figure 1 is a perspective view of a transverse suspension device in accordance with the present invention;

Figure 2 is a trailing end view of the transverse suspension device of figure 1;

Figure 3 is a sectional view through the transverse suspension device of figure 1;

Figure 4 is a partial view of the right knee joint showing the femoral and tibial tunnels prepared for ACL reconstruction;

Figure 5 is a partial view of the right knee joint illustrating the use of an A-Tech guide;

Figure 6 is the view of figure 4 showing the drilling of the transverse tunnel;

Figure 7 is a view of figure 4 showing the guide wire and tap in position;

Figure 8 is a view of figure 4 showing the graft being pulled into position;

Figure 9 is a cross sectional view of a dilation device;

Figure 10 is a cross sectional view of the femoral tunnel prior to location of the suspension device;

Figure 11 is a cross sectional view of the femoral tunnel with the suspension device in place; and

Figure 12 is a view of figure 4 showing the transverse suspension device stably securing the graft loop in the femoral tunnel.

Referring to figures 1, 2 and 3, a transverse suspension device 2 has a tubular body section 4 and a co-axial head section 6 joined to and protruding from the leading end 8 of the body section 4. The transverse suspension device 2 is cannulated along the length of the axis thereof so that it may be passed along a guide wire in use. The body section 4 is externally screw threaded along its entire

length and the head section 6 includes a trailing part 10 coaxial with the body section 4 but of a narrower outer diameter and a frustoconical nose section 12 extending from the leading end of the trailing part 10 and having the narrower end forming the leading end of the nose section. The tip of the nose section is rounded in a convex manner and includes the exit port 14 of the cannulated hole of the device at its centre.

The hollow interior of the device extends from the trailing end in the form of a central tubular recess which is stepped into a radially narrower keyhole section 20, midway along the length of the body section, which extends forwardly through the remainder of the body section as far as the leading end thereof. The keyhole section 20 includes three radially inwardly directed longitudinally extending vanes 22, 24 and 26. The vanes are equally circumferentially spaced apart around the interior wall of the tube but have their trailing ends slightly axially recessed with respect to the beginning of the keyhole section. Each vane has a leading face which is arcuate in end section and a trailing face which is substantially flat in end section and extends radially away from the longitudinally extending apex of the vane back to the internal circumferential wall of the hollow keyhole section. Thus, each vane forms a radially inwardly directed ridge which ridge extends longitudinally along the length of the keyhole section and provides the means for a suitable co-engaging tool to engage therewith for screwing the device into position during surgery.

Referring to figure 4, a partial view of the right knee joint 30 includes a tibia section 32 and a femur section

34 articulating therewith in the usual manner. In the illustration shown, the posterior cruciate ligament 36 is shown extending between the tibia and the femur but the anterior cruciate ligament is missing. A tibial tunnel 38 of standard construction extends between the anterior surface of the tibia and the tibial plateau. A femoral tunnel 40 extends from the intercondylar notch towards the lateral femoral aspect and includes a passing pin tunnel 42 which extends from the proximal end 44 of the femoral tunnel to exit at the lateral femoral aspect of the femur 46. The method of preparation of the tibial and femoral tunnels are in accordance with standard techniques known in the art.

Referring to figure 5, a transverse femoral guide 48 of known construction includes a femoral locator 50 comprising an elongate straight rod 52 with a femoral locator head 54 located at the proximal end thereof and which is sized to fit within the femoral socket 40. The straight rod section 52 is designed to extend from an anchor section 56, through the tibial tunnel and intercondylar notch. An arcuate guide arm 58 of standard construction extends from the lateral side of the anchor 56 in an arcuate manner and includes an adjustable sleeve section 50 for multiple position fixation with respect thereto. The head 62 of the guide arm sleeve 60 accommodates a cannulated guide wire bullet 64 which extends therethrough. The positioning of the head of the sleeve 62 is such that it extends parallel with the femoral locator head 54 and the cannulated bullet extends through an appropriately sized perpendicular aperture in the head of the guide arm sleeve 62 so that it may be advanced towards the head of the femoral locator. In use,

a small lateral incision is made on the surface of the knee joint to remove any soft tissue so that the cannulated bullet may be advanced until it firmly locates on the lateral epicondyle. The length of the transverse tunnel to be drilled can be determined from the measurements on the transverse bullet according to known techniques. The 2.4mm guide wire may then be drilled through the femur until it touches the femoral locator. Thereafter, the guide 48 may be removed together with the femoral locator leaving the guide wire 66 in position. The guide wire 66 is then advanced to penetrate bone on the opposite wall of the femoral tunnel by approximately 1cm.

Referring to figure 6, the guide wire 66 is shown as it is being advanced towards the opposite wall of the femoral tunnel. Thereafter, it may be over drilled with an 8mm cannulated drill 68 to create the transverse tunnel 70 which intersects with the femoral tunnel 40. An arthroscope (not shown) may be inserted into the femoral tunnel via the intercondylar notch to assess penetration of the drill 68 into the femoral socket, as the drill should not penetrate the opposite wall of the femoral socket. At this point in the procedure, the 2.4mm guide wire pin 66 may be removed and replaced with a thinner 1mm guide wire of the transverse screw. Thereafter, the cannulated drill 68 may be removed.

Referring to figure 7, a cannulated tap 72 is shown being advanced along the transverse tunnel 70 so as to pre-thread the tunnel in preparation for receiving the transverse suspension device screw. After tapping of the transverse tunnel 70 is complete, the tap 72 may be

removed leaving the guide wire in position. The guide wire is then retracted away from the medial wall of the femoral tunnel to provide a gap which is sufficient to allow insertion of the graft into the femoral tunnel.

Referring to figure 8, a graft loop 74 is shown located in position in the femoral tunnel 40. The graft includes sutures 76 threaded therethrough and tied at the proximal end to the end of a passing pin 78. In practice, the passing pin is advanced through the tibial tunnel, intracondylar notch and femoral tunnel and passed out through the passing pin tunnel 42 to appear at the lateral femoral aspect. The sutures may then be pulled to locate the loop of the graft in the correct position in the femoral tunnel. Care should be taken so that the face of the loop faces the intersection with the transverse tunnel 70. The screw guide wire extending down the transverse tunnel 70 may then be located under the loop using an arthoscope 80 via the same transverse tunnel 70. The arthoscope 80 and guide wire may be advanced together under the loop and once successively located the arthoscope may be retracted and removed taking care to retain the guide wire in position.

Referring to figure 9, a dilation device 100 is shown having a tubular shaft 102, a handle section 104 and a nose section 108. The nose section 108 is frustoconical in shape, and has a rounded leading end 110. The frustoconical section extends distally from a shoulder section 106 at the trailing end thereof, the said shoulder section extending proximally with a constant cross-section as far as the shaft 102, co-axial therewith but of a slightly larger cross-section than the shoulder. The

dilation device 100 is cannulated 112 along the entire length thereof so as to be passed along the guide wire such that it dilates the graft loop 74 as it passes transversely through the bone tunnel. The dilation device 100, is advanced along the guide wire with sufficient force to create a recess in the opposite wall of the femoral tunnel in which the frustoconical nose section 12 of the suspension device 2 may be accommodated. Accordingly, the dilation device is suitably dimensioned to be complimentary to the suspension device in this respect. The dilation device 100 is then retracted leaving the graft loop 74 sufficiently dilated such that the suspension device 2 can be advanced therethrough. When retracting the dilation device 100, care is taken to retain the guide wire in position.

Referring to figure 10, the cannulated screw is shown located over the guide wire and advancing towards the dilated graft loop 74

Referring to figure 11, the suspension device 2 is shown fully advanced into the femoral tunnel with its frustoconical nose section 12 embedded in the recess 13 formed in the opposite wall of the femoral tunnel. The body section 4 being of a wider diameter than the trailing part of the head section 6, provides an annular abutment for the graft loop residing on the trailing part 10 and as the suspension device advances the annular abutment urges the graft loop against the opposite wall of the bone tunnel thus encouraging the graft and the bone to graft to each other.

Thereafter, the guide wire may be removed. The final position of the cannulated transverse suspension device screw is shown in figure 12 with the outer wall of the head of the screw and the leading end of the body section urging the graft into contact with the walls of the femoral tunnel. The trailing ends of the graft 82, 84,86, 88 may be fixed to the tibia in accordance with the surgeons preference and in accordance with techniques known in the art.

A suitable type of graft for use with the present invention is a double-looped semitendinosus and gracilis (DLSTG) hamstring graft which may be prepared in accordance with techniques known in the art.

A suitable material for the screw would be a combination of ceramic and polymer materials. A suitable ceramic component could be tri-calcium phosphate or ceramic hydroxyapetite. However, any suitable bio ceramic may be used. The polymer component may incorporate poly lactic acid to provide good biocompatibility.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination,

except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

The invention is not restricted to the details of the foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

CLAIMS

1. A transverse suspension device for ACL graft fixation in a femoral bone tunnel comprising a body section and a smooth head section forming the leading end of the device, the body and smooth head sections each being cannulated along the entire lengths thereof; the head section comprising a recess engaging section extending proximally from the distal end thereof and operable to engage with a recess formed in the bone tunnel, and a graft loop support section between the recess engaging section and the body section adapted to stably support the graft loop thereover.

2. A transverse suspension device for ACL graft fixation in a femoral bone tunnel comprising a body section and a smooth head section forming the leading end of the device, the body and smooth head sections each being cannulated along the entire lengths thereof; the head section comprising a recess engaging section extending proximally from the distal end thereof and operable to engage with a recess formed in the bone tunnel, and an abutment surface located between the body section and the recess engaging section adapted to urge the graft against the opposite wall of the bone tunnel, in use.

3. A device as claimed in claim 1, which comprises an abutment surface located between the body section and the recess engaging section adapted to urge the graft against the opposite wall of the bone tunnel, in use.

4. A device as claimed in claim 2, which comprises a graft loop support section between the recess engaging section and the body section adapted to stably support the graft loop thereover.

5. A device as claimed in any preceding claim, wherein the device is cannulated along the entire length thereof.

6. A device as claimed in any preceding claim, wherein the head section extends forwardly from the leading end of the body section.

7. A device as claimed in any preceding claim, wherein the body section is suitably adapted for secure fixation, in use, in a tunnel transverse to the femoral tunnel.

8. A device as claimed in any preceding claim, wherein at least a part of the smooth head tapers outwardly from the leading end thereof to form a tapered section of the head.

9. A device as claimed in any of claims 1-8, wherein the graft loop support section is of constant cross-section.

10. A transverse suspension device for ACL graft fixation in a femoral bone tunnel comprising a body section and a smooth head section forming the leading end of the device, the body and smooth head sections each being cannulated along the entire lengths thereof; the head section comprising a recess engaging section extending proximally from the distal end thereof and operable to engage with a recess formed in the bone tunnel, and a non tapered graft loop support section between the recess engaging section and the body section adapted to stably support the graft loop thereover.

11. A transverse suspension device for ACL graft fixation in a femoral bone tunnel comprising a body section and a smooth head section forming the leading end of the device, the body and smooth head sections each being cannulated along the entire length thereof; the head

section comprising a recess engaging section extending proximally from the distal end thereof and operable to engage with a recess formed in the bone tunnel, and a flange located between the body section and the recess engaging section to urge the graft against the opposite wall of the bone tunnel, in use.

12. A device as claimed in claim 10, which comprises a flange located between the body section and the recess engaging section adapted to urge the graft against the opposite wall of the bone tunnel in use.

13. A device as claimed in claim 11, which comprises a non tapered graft loop support section between the recess engaging section and the body section adapted to stably support the graft loop thereover

14. A device as claimed in any preceding claim, wherein the flange includes an annular abutment surface on the distal face thereof to engage with the graft loop and urge it towards the opposite wall of the bone tunnel, in use.

15. A method of ACL graft ligament fixation comprising the steps of:-

forming a femoral tunnel for graft fixation therein;

forming a transverse tunnel for intersecting the femoral tunnel;

locating a graft loop in the femoral tunnel in such a manner that the open face of the loop faces the intersection of the transverse tunnel,

passing at least a part of the head section of a transverse suspension device according any preceding

claim through the graft loop via the transverse tunnel.

16. A method according to claim 15, wherein after location of the graft loop in the femoral tunnel, a guide wire is advanced thereunder from the transverse tunnel using a suitable viewing device such as an arthroscope.

17. A method according to claim 16, wherein the suspension device is passed along the guide wire after the guide wire is advanced under the graft loop.

18. A method according to any of claims 15-17, wherein the head of the device is advanced as far as the opposite wall of the femoral tunnel.

19. A method according to any of claims 15-17, wherein the head of the device is advanced as far as a distal head of a recess formed in the opposite wall of the femoral tunnel.

ABSTRACT

A transverse suspension device (2) for ACL graft fixation in a femoral tunnel (40) comprising a body section (4) and a smooth head section (6) forming the leading end of the device (2), the body and smooth head sections (4,6) each being cannulated along the entire lengths thereof; the head section (6) comprising a recess engaging section (12) extending proximally from the distal end thereof and operable to engage with a recess (13) formed in the bone tunnel (40), and a graft loop support section (10) between the recess engaging section (12) and the body section (4) adapted to stably support the graft loop (74) thereover.

[Figure 1]

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Fig 1

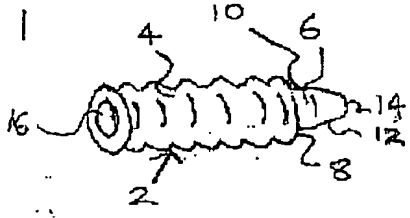

Fig 2

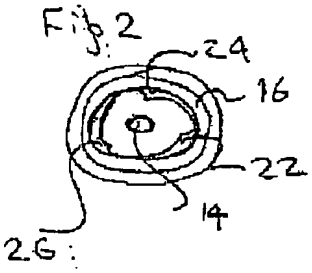

Fig 3.

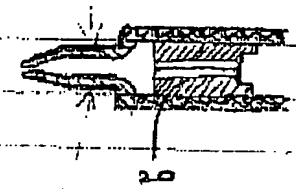

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Fig 4

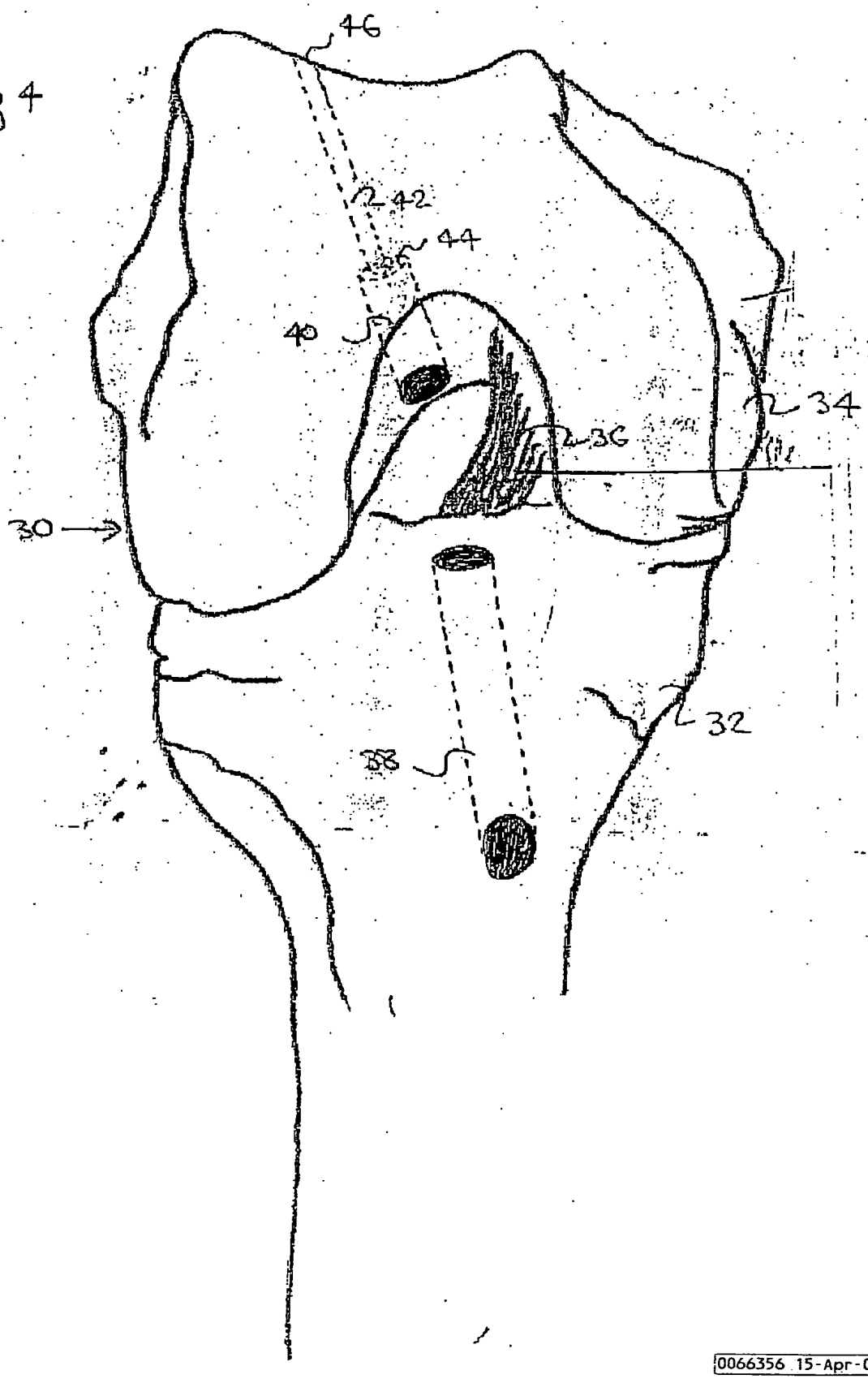

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Fig 5

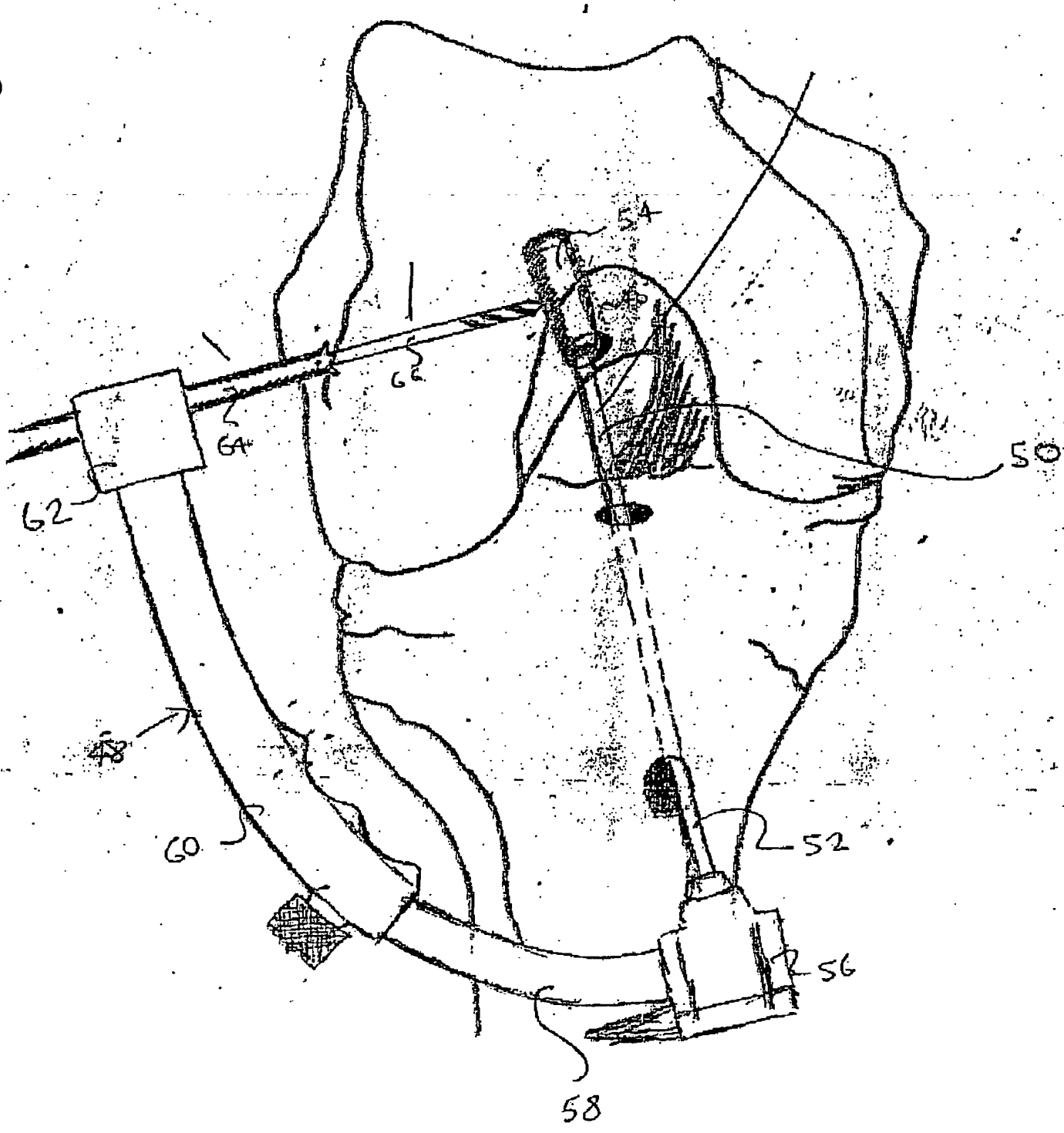

Fig 6

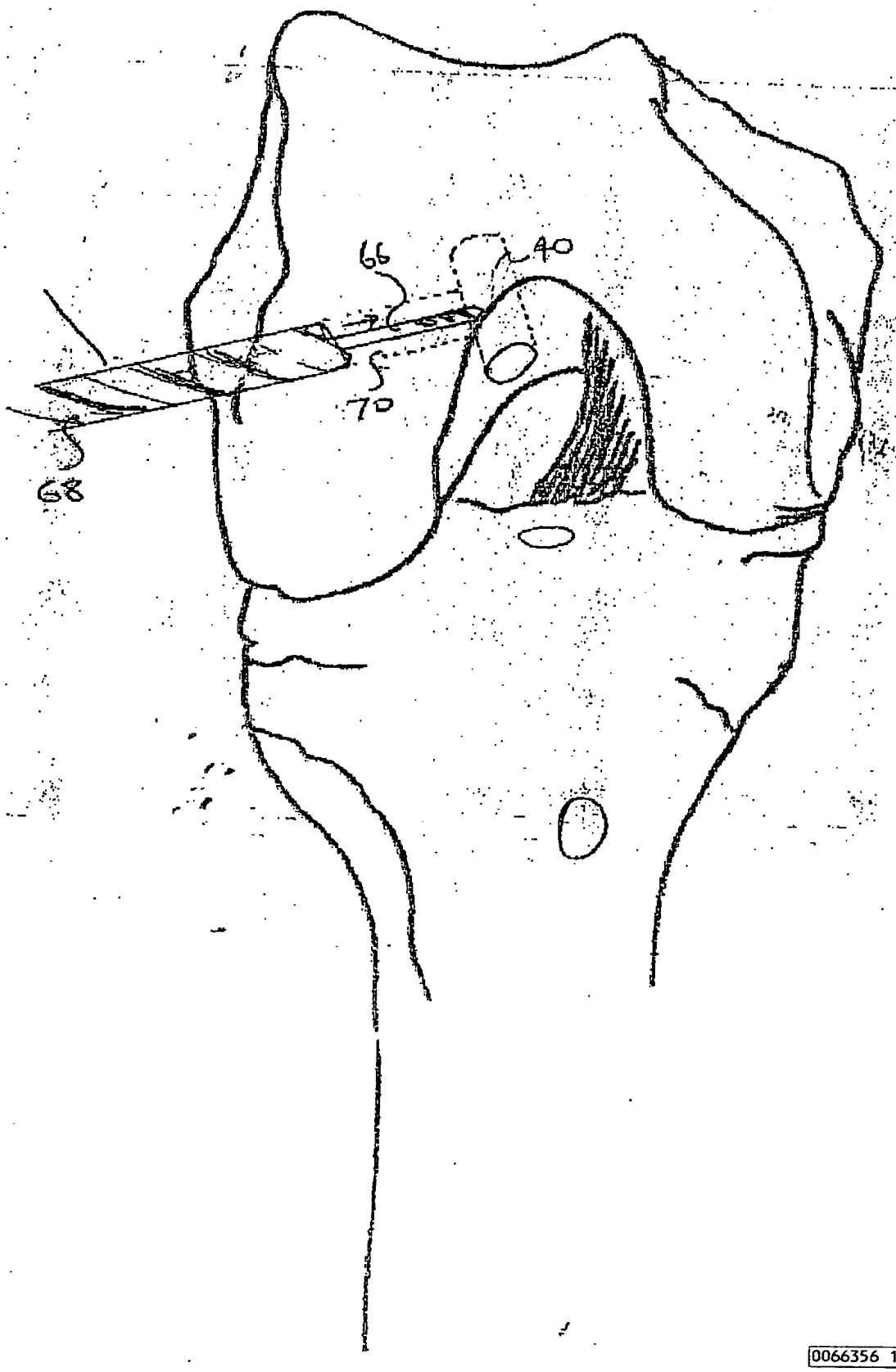

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Fig.7

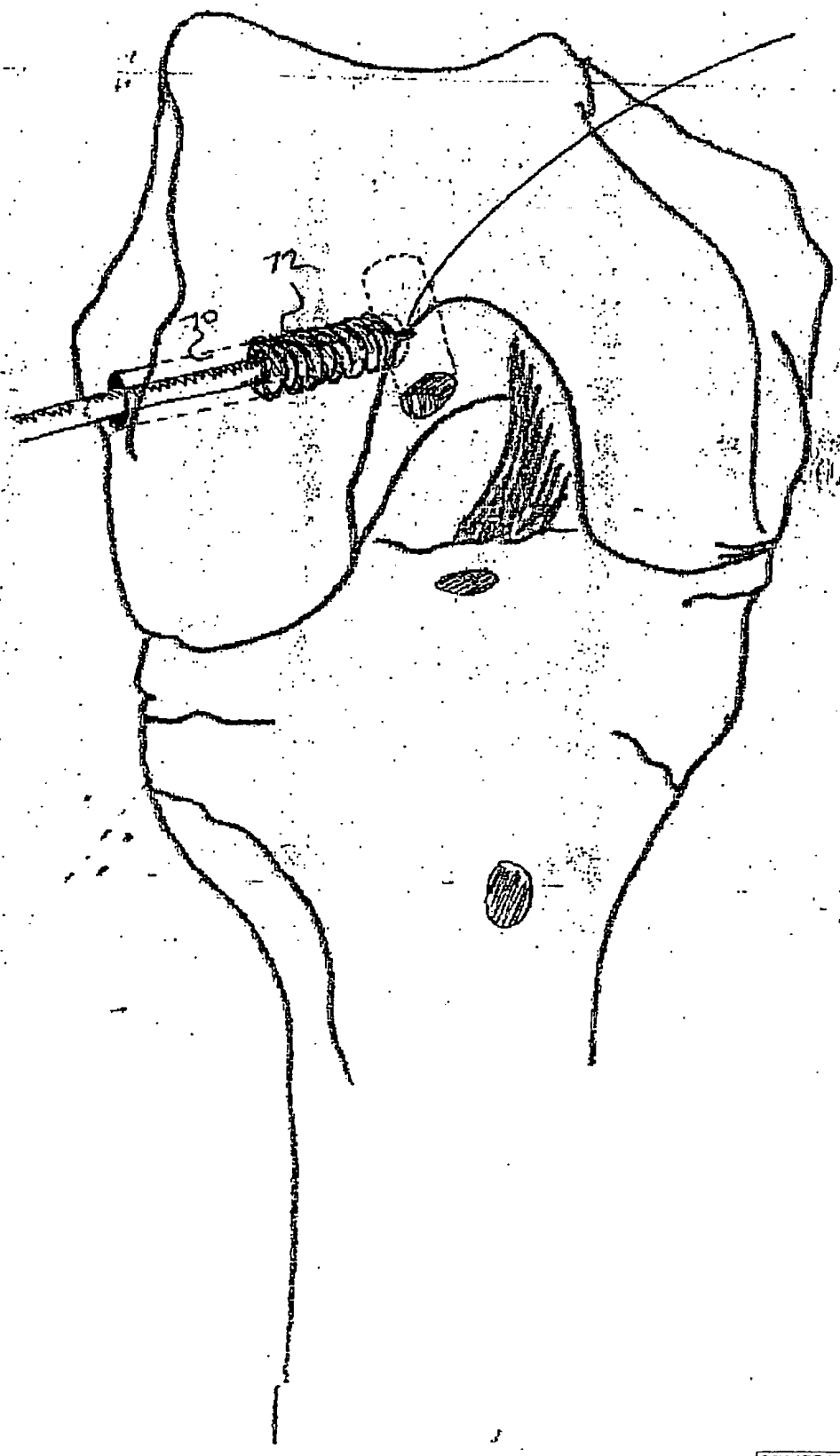

Fig 8

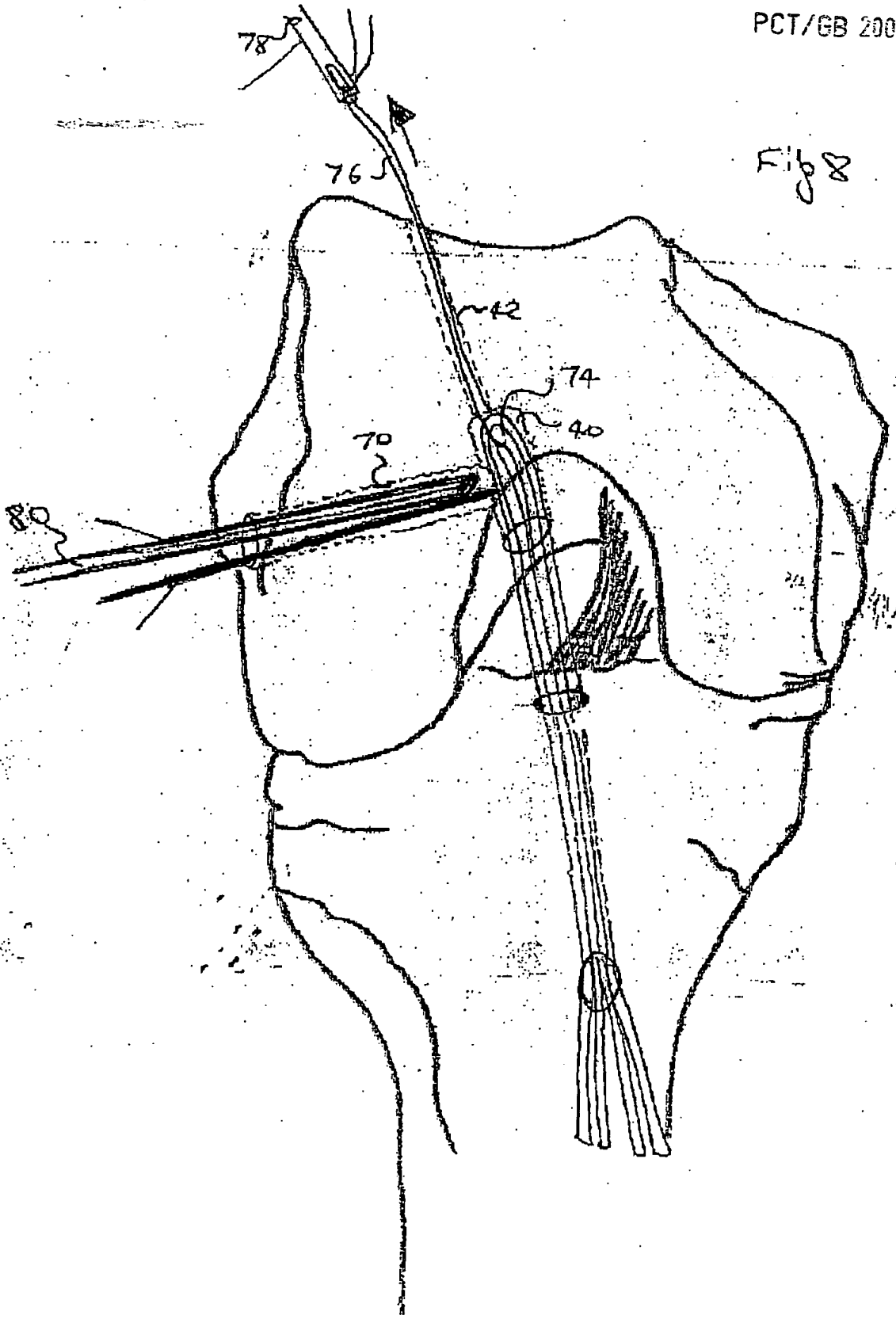

Fig 9

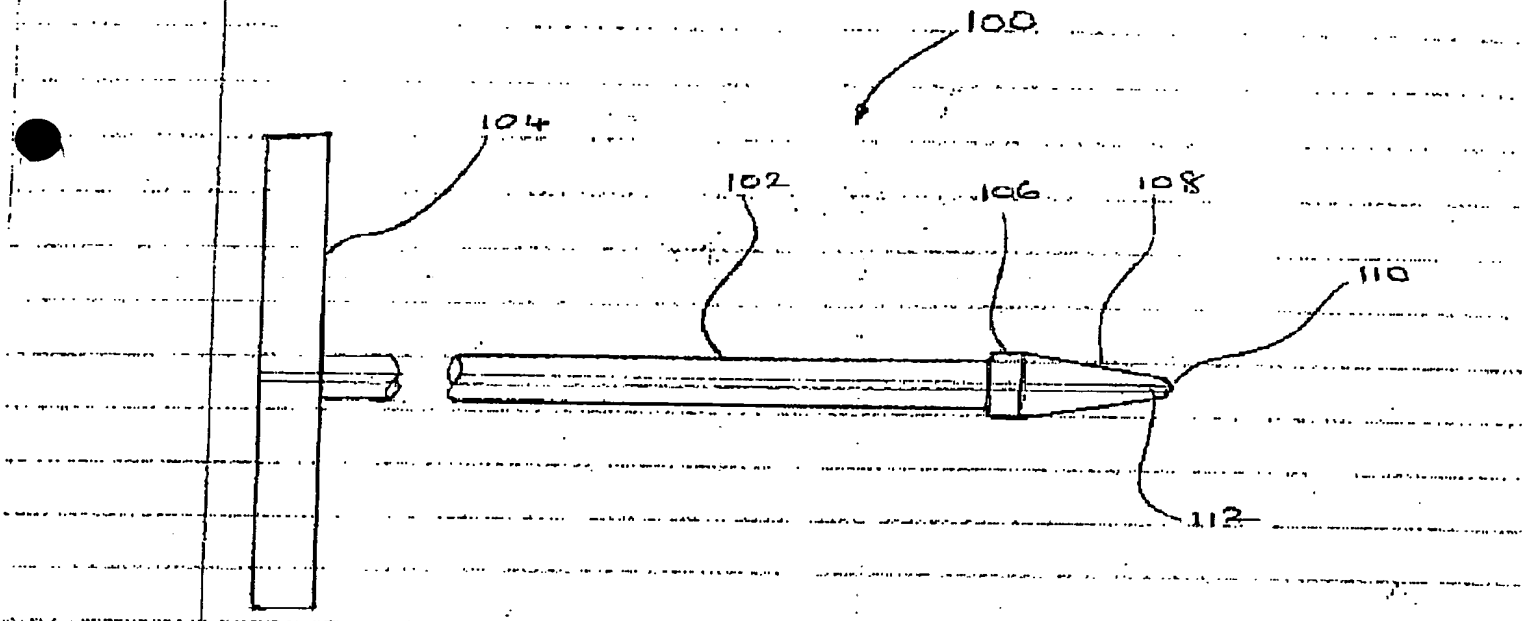

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Fig 10

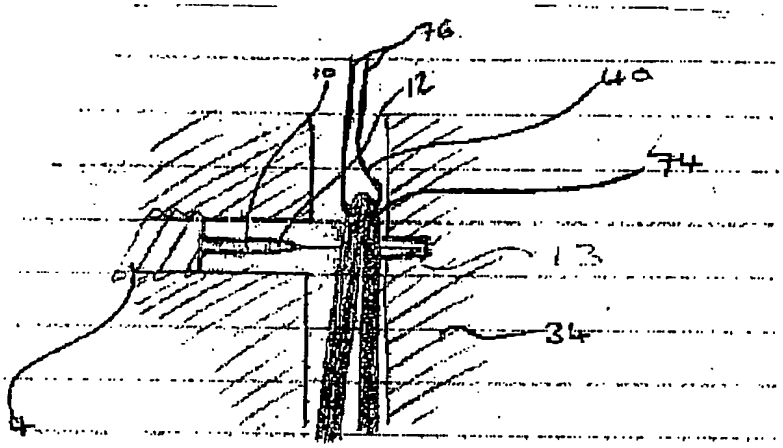

Fig 11

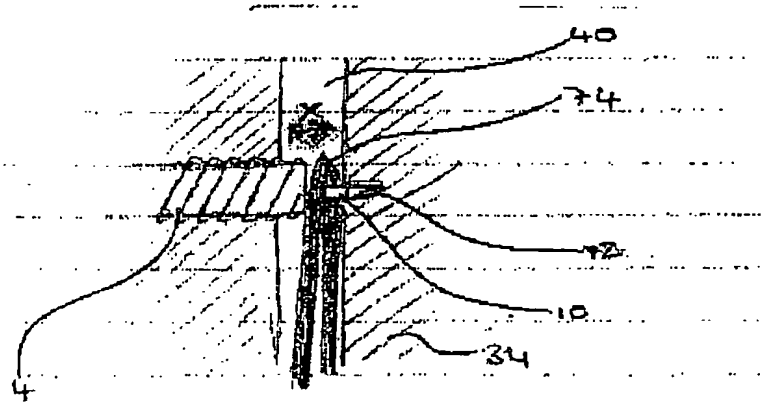

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Fig 12